

Message Text

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ORIGIN HEW-06

INFO OCT-01 AF-06 ARA-10 ISO-00 OES-05 /028 R

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DHEW/FDA/JRWEINROTH, M.D.

APPROVED BY OES/SCI/BMP:MBEAUBIEN

DHEW OIH/MACODDING

ARA/CAR:DASTRASSER(INFO)

AF/S:RJDOLS(INFO)

----- 044272

R 092129Z APR 75

FM SECSTATE WASHDC

TO AMEMBASSY SANTO DOMINGO

AMEMBASSY PRETORIA

UNCLAS STATE 079609

E.O. 11652: NA

TAGS: OGEN, ETRD, TBIO, DR, SF

SUBJ: FDA ADVISORY-DIAGNOSTIC MEDICAL DEVICE-BACTERIAL CONTAMINATION

1. FDA ADVISES THAT THE PRODUCT STERILE LUMBAR PUNCTURE TRAYS FOR LUMBAR PUNCTURE IN ADULTS AND PEDIATRIC/INFANTS-CATALOG NO. 4302B LOT NO. C4L032B PEDIATRIC/INFANT, CATALOG NO. 4303B, LOTMO. C4K329X ADULT, AND CATALOG NO. 4303B, LOT NO. C4N220X ADULT, MANUFACTURED BY PHARMASEAL LABORATORIES, IRWINDALE, CALIF. 91201, PACKAGED IN UNIT CARTONS LABELED IN PART: " LUMBAR PUNCTURE TRAYS STERILE SPINAL NEEDLE GUAGE SPINAL NEEDLE CATALOG NO CONTENTS: DIRECTIONS FOR USE CAUTION: FEDERAL (U.S.A.) LAW PROHIBITS PHARMASEAL LABORATORIES, GLENDALE CALIF. 91201, ARE BEING RECALLED FROM THE MARKET BECAUSE OF THE FINDING OF NON-VIABLE GRAM NEGATIVE RODS IN THE SPINAL FLUID COLLECTION TUBES OF THE LUMBAR PUNCTURE TRAYS.

2. THE HAZARD INVOLVED WITH THESE LOTS IS THE POSSIBLE MISDIAGNOSIS OF

PATIENTS, INASMUCH AS THE COLLECTION TUBES MAY CONTAIN GRAM NEGATIVE RODS, RESULTING IN A MISDIAGNOSIS OF SPINAL MENINGITIS.

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3. FOREIGN CONSIGNEES AS FOLLOWS:

- (1) J. GASSO-GASSO C FOR A, SANTO DOMINGO, DOMINICAN REPUBLIC
- (2) M. STABLER PTY. INC., JOHANNESBURG, SOUTH AFRICA.

POST ARE REQUESTED TO DETERMINE IF FOREIGN CONSIGNEES HAVE RECEIVED
RECALL LETTERS DETAILING NATURE OF PROBLEM.
KISSINGER

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Message Attributes

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Margaret P. Grafeld
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05 JUL 2006

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